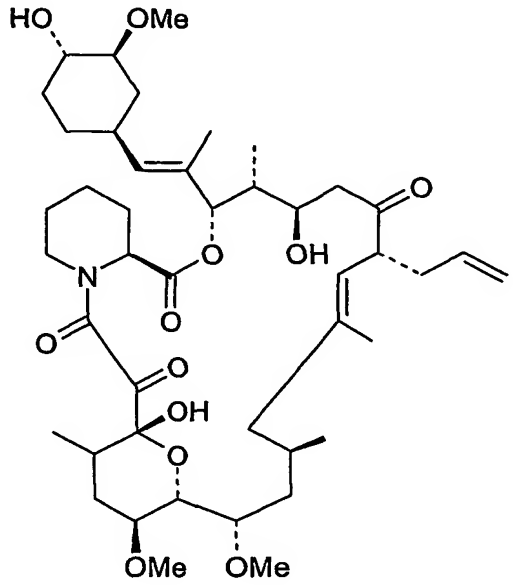
We Claim:

1. An isolated microorganism *Streptomyces glaucescens* MTCC 5115.

2. A fermentation process for producing tacrolimus (FK-506) of Formula I,



FORMULA I

the process comprising using isolated *Streptomyces glaucescens* MTCC 5115.

3. A process for producing tacrolimus, the process comprising the steps of culturing a strain of *Streptomyces glaucescens* MTCC 5115 or mutant thereof under submerged aerobic fermentation conditions in an aqueous nutrient medium; and isolating the tacrolimus from said medium.

4. The process of claim 3, wherein the nutrient medium comprises one or more of carbon source, nitrogen source and mineral salts.

5. The process of claim 4, wherein the carbon source is a carbohydrate medium.

6. The process of claim 5, wherein the carbohydrate source comprises one or more of glucose, xylose, galactose, glycerol, dextrose, starch, dextrin, maltose, polyethylene glycol, soybean oil, rhamnose, raffinose, arabinose, mannose, salicin and sodium succinate.

7. The process of claim 4, wherein the nitrogen source comprises one or more of yeast extract, soy peptone, soybean meal, cottonseed meal, corn steep liquor, wheat peptone, maize gluten, milk powder and wheat germ.

8. The process of claim 4, wherein the mineral salts comprises one or more of salts of calcium, magnesium, sodium, cobalt, copper and potassium.

9. The process of claim 4, wherein the nutrient medium further comprises a defoaming agent.

10. The process of claim 3, wherein during fermentation the temperature is maintained from about 20°C to about 40°C.

11. The process of claim 10, wherein the temperature is maintained from about 24° to about 35°C.

12. The process of claim 3, wherein during fermentation pH is maintained from about 6.0– 8.0.

13. The process of claim 12, wherein the pH is maintained from about 6.8-7.5.

14. The process of claim 3, wherein the nutrient medium is a liquid culture broth.

15. The process of claim 3, wherein the isolation of tacrolimus comprises one or more of filtration, centrifugation, concentration, concentration under reduced pressure, lyophilization, acidification, extraction with a suitable solvent, treatment with adsorbents, treatment with resins, purification, and crystallization.

16. The process of claim 15, further comprising recrystallizing the isolated tacrolimus.

17. The process of claim 16, further comprising forming the product obtained into a finished dosage form.

18. A method of treating or preventing a transplantation rejection of organs or tissues in a warm-blooded animal, the method comprising providing a dosage form to the warm-blooded animal that includes the tacrolimus obtained by the process of claim 3.

19. The method of claim 18, wherein the organ or tissue is heart, kidney, liver, medulla ossium, and skin.

20. A pharmaceutical composition comprising a therapeutically effective amount of tacrolimus (FK-506) obtained by the process of claim 3; and one or more pharmaceutically acceptable carriers, excipients or diluents.